

## **EXHIBIT 4**



## In the Missouri Court of Appeals Eastern District

### DIVISION TWO

MIASIA BARRON, et al.,	)	No. ED103508
	)	
Plaintiffs,	)	Appeal from the Circuit Court
	)	of the City of St. Louis
and	)	
	)	
MADDISON SCHMIDT,	)	
	)	
Plaintiff/Respondent,	)	
	)	
v.	)	
	)	
ABBOTT LABORATORIES, INC.,	)	Honorable Steven R. Ohmer
	)	
Defendant/Appellant.	)	Filed: November 8, 2016

### Introduction

Abbott Laboratories, Inc. (Appellant) appeals from the judgment of the trial court entered upon a jury verdict in favor of Minnesota resident Maddison Schmidt (Respondent), a minor, brought by her adoptive parents Gary and Tammy Schmidt as her Next Friends,<sup>1</sup> for personal injury. The jury awarded actual damages in the amount of \$15,000,000 and punitive damages in the amount of \$23,000,000. We affirm.

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<sup>1</sup> Respondent's next friend was initially her biological mother, Tiffany Vititoe, who took Depakote for her epilepsy as prescribed by her physician, Dr. Robert G. Jacoby (Dr. Jacoby), while she was pregnant with Respondent in Minnesota. Respondent was born with and suffers from spina bifida; microcephaly; ocular coloboma, which is a congenital eye defect; brain malformations; and cognitive impairment. Respondent is mentally handicapped and has an IQ between 55 and 61 (bottom 1%) and is paralyzed below the waist and confined to a wheelchair. Respondent has had several surgeries, including the placement of a shunt in her skull, shunt revisions, and spinal surgeries.

Factual and Procedural Background

This a personal injury case in which 24 plaintiffs, by their next friends, joined to bring a nine-count petition against Appellant, the manufacturer of the antiepileptic drug (AED) Depakote, for birth defects they suffered as a result of their biological mothers' being prescribed and ingesting the drug while they were in utero. The nine counts relate to Appellant's manufacture, sale, and marketing of Depakote and allege (1) strict products liability; (2) negligence; (3) gross negligence; (4) breach of implied warranty; (5) breach of express warranty; (6) misrepresentation by omission; (7) fraud and misrepresentation; (8) intentional infliction of emotional distress; and (9) negligent infliction of emotional distress. The petition specifically requests, in addition to compensatory damages, punitive damages.

When Respondent's mother became pregnant with her, the label for Depakote<sup>2</sup> had a black box warning that stated:

VALPROATE CAN PRODUCE TERATOGENIC EFFECTS SUCH AS  
NEURAL TUBE DEFECTS (E.G., SPINA BIFIDA). ACCORDINGLY, THE  
USE OF DEPAKOTE TABLETS IN WOMEN OF CHILDBEARING  
POTENTIAL REQUIRES THAT THE BENEFITS OF ITS USE BE WEIGHED  
AGAINST THE RISK OF INJURY TO THE FETUS.

During litigation, Appellant vigorously contested venue in the City of St. Louis and joinder of the plaintiffs not living in the City of St. Louis; sought severance of the non-City of St. Louis plaintiffs' claims and alleged *forum non conveniens* for the out-of-state plaintiffs;<sup>3</sup> filed motions, writs, removal to federal court; and sought judgment notwithstanding the verdict (JNOV), directed verdict (DV), remittitur, and a new trial. None of these efforts was successful for Appellant. This appeal follows.

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<sup>2</sup> Depakote is also known as valproate or valproic acid.

<sup>3</sup> The plaintiffs and their parents as next friends came from Florida, Georgia, Illinois, Louisiana, Minnesota, Missouri, Montana, New York, North Carolina, Oklahoma, Pennsylvania, Tennessee, and Texas.

Points on Appeal

In its first point, Appellant claims the trial court erred in denying its motion to transfer Respondent's claims to St. Louis County because St. Louis County was the only potentially proper Missouri venue for Respondent's claims under Section 508.010<sup>4</sup> in that Respondent was first injured outside of Missouri and Appellant's registered agent is located in St. Louis County.

In its second point, Appellant asserts the trial court erred in denying its motion to sever Respondent's and the other plaintiffs' claims, because (a) the 24 plaintiffs' claims did not arise out of the same transaction, occurrence, or series of transactions or occurrences in that the plaintiffs' mothers were prescribed Depakote at different points in time by different physicians under different circumstances and plaintiffs alleged different injuries, and (b) because it was impossible to conduct a fair trial of all the plaintiffs' claims in that there were significant factual and legal differences between those claims.

In its third point, Appellant maintains the trial court erred in denying its motions for DV and JNOV on Respondent's failure to warn claim because the Depakote label was adequate as a matter of Minnesota law in that the label (a) attracted the attention of those to whom it was directed, (b) explained the mechanism and mode of injury, and (c) explained how to safely use the product to avoid injury.

In its fourth point, Appellant contends the trial court erred in denying its motions for DV and JNOV on Respondent's demand for punitive damages because Respondent did not present clear and convincing evidence Appellant deliberately disregarded the rights and safety of others in that Appellant warned prescribing physicians of Depakote's risk of spina bifida via a black box warning.

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<sup>4</sup> All statutory references are to RSMo 2012, unless otherwise indicated.

In its fifth point, Appellant argues the trial court committed cumulatively prejudicial evidentiary errors in (a) admitting an expert warning opinion which had not been disclosed prior to trial, (b) admitting evidence of marketing and promotional materials to which the prescribing physician was never exposed, and (c) admitting evidence of Appellant's financial condition during the compensatory damages phase of the trial.

### Discussion

#### Venue, Joinder, and Severance

Points I and II are discussed together because they are inextricably intertwined, particularly under the facts of this case.

#### Venue and Joinder

Appellant claims the only potentially proper Missouri venue for tort claims in which Respondent, as plaintiff, was first injured outside of Missouri is the county in which Appellant's registered agent is located, which is St. Louis County, citing Section 508.010.5. However, Respondent was joined with 23 other plaintiffs, two of which were first injured in the City of St. Louis, creating proper venue in the City of St. Louis pursuant to Section 508.010.4. Appellant claims the plaintiffs' claims were improperly joined and their claims should have been severed pursuant to Appellant's motion, which the trial court denied.

Venue and joinder are intertwined in the law. The proper joinder of plaintiffs is relevant to the determination of venue under Section 508.010.<sup>5</sup> The issues of proper venue are contingent upon whether there is proper joinder of parties. State ex rel. Allen v. Barker, 581 S.W.2d 818, 824 (Mo. 1979).

Section 508.010.4 provides:

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<sup>5</sup>Section 508.010 was revised in 2005. State ex rel. Nixon v. Dally, 248 S.W.3d 615, 619 (Mo.banc 2008).

Notwithstanding any other provision of law, in all actions in which there is any count alleging a tort and in which the plaintiff was first injured in the state of Missouri, venue shall be in the county where the plaintiff was first injured by the wrongful acts or negligent conduct alleged in the action.<sup>6</sup>

In the instant case, Respondent alleged plaintiffs Jerricka Marshall and Jerrinee Marshall were first injured in the City of St. Louis when they were exposed to Depakote when their mother, Sheena Hill, ingested the drug at her home in the City of St. Louis. Section 508.010.14 provides: “A plaintiff is considered first injured where the trauma or exposure occurred rather than where symptoms are first manifested.” Venue was thus proper as to these two plaintiffs in the City of St. Louis, and if the other plaintiffs were properly joined with them in their claims, then venue is proper to all of them under Section 508.010.4.

Rule 52.05(a)<sup>7</sup> permits joinder in separate cases arising out of the same transaction, occurrences, or series of transactions or occurrences and if any question of law or fact common to all of them will arise in the action. Dally, 248 S.W.3d at 616. Rule 52.05(a) provides:

(a) Permissive Joinder. **All persons may join in one action as plaintiffs if they assert any right to relief jointly, severally, or in the alternative in respect of or arising out of the same transaction, occurrence or series of transactions or occurrences and if any question of law or fact common to all of them will arise in the action.** ... A plaintiff or defendant need not be interested in obtaining or defending against all the relief demanded. Judgment may be given for one or more of the plaintiffs according to their respective rights to relief, and against one or more defendants according to their respective liabilities.

(Emphasis added.) Rule 52.05(a) requires that the series of occurrences be related by a common question of law or fact, a requirement that is readily apparent here because of the common factual question as to the origin of the plaintiffs’ injuries. Dally, 248 S.W.3d at 617.

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<sup>6</sup>The Missouri legislature has mandated that singular terms in its statutes should be construed as including their plural forms unless there be something in the subject or context repugnant to such construction. State ex rel. BJC Health Sys. & Christian Hosp. v. Neill, 121 S.W.3d 528, 530 (Mo.banc 2003).

<sup>7</sup> All rule references are to Mo. R. Civ. P. 2012, unless otherwise indicated.

Here, the commonalities among the 24 plaintiffs are, first and foremost, each alleged birth defect injuries from the drug Depakote, which their mothers took by prescription during their pregnancies. The plaintiffs alleged Appellant is the only manufacturer, seller, and marketer of Depakote and, as such, was responsible for proper warnings about the potential side effects in the form of birth defects for the children of women taking Depakote while pregnant. The plaintiffs each made the same allegations in the petition regarding strict products liability, negligence, insufficient warning, breach of warranty, and infliction of distress regarding Depakote against one and the same defendant, Appellant. The plaintiffs asserted rights to relief against Appellant jointly and alleged facts which gave rise to common questions of law or fact for Appellant.

This is a single defendant case. There are 24 plaintiffs. All 24 plaintiffs assert Appellant's drug, Depakote, caused their birth defects. As to each and every plaintiff, the petition pled:

[Appellant's] Depakote was defectively designed, inadequately tested, dangerous to humans and [the] unborn and lacked proper warnings as to the true danger associated with its use, and Plaintiffs suffered injury as a result of the mother's ingestion of Depakote.

Missouri law clearly allows for the joinder of unrelated plaintiffs who allege injury from the same conduct of the same defendant. See Kelley v. National Lead Co., 210 S.W.2d 728, 729 (Mo.App. 1948); Saeger v. Lakeland Development Co., 350 S.W.2d 820, 822 (Mo.App. 1961). Plaintiffs, as joined, asserted claims against Appellant for the same conduct, containing common questions of fact and law concerning what information Appellant possessed concerning Depakote's harmful effects, what information Appellant elected to disclose to physicians and patients about those harmful effects, and what information Appellant was required by law to disclose about those effects.

All of the substantive pleadings are common. The petition outlined 14 paragraphs of common factual claims regarding Appellant's knowledge and warning failures. Of the 113 paragraphs in the petition, all but the 24 that describe the individual plaintiffs apply to every plaintiff's case. On the face of the pleadings, these cases are properly joined.

The differences among the 24 plaintiffs in this case alleged by Appellant are (1) they come from 13 different states; (2) they vary in age, with the oldest being born in 1992 and the youngest in 2010, and thus were exposed to Depakote at varying times; (3) the mothers were prescribed Depakote by different physicians under different circumstances; and (4) the plaintiffs allege varying injuries. These differences are insignificant and inconsequential in substance when compared with the commonalities. Furthermore, Appellant's argument suggests the Court should look solely from the perspective of the particular circumstances of each plaintiff's mother's use of Depakote as constituting the relevant "transactions" and not from the perspective of Appellant's nationwide promulgation and marketing of Depakote. Here, plaintiffs have shown significant substantive commonalities directly related to the central issue in this case, Appellant's negligent dissemination of its drug Depakote.

The fact Depakote was prescribed to the plaintiffs by different physicians is not controlling on the question of joinder. Nor are the claimed differences in the Depakote-induced birth defects sustained by the plaintiffs the issue here. See Mosley v. General Motors Corp., 497 F.2d 1330, 1334 (8<sup>th</sup> Cir. 1974) ("The fact that each plaintiff may have suffered different effects ...is immaterial for the purposes of determining the common question of law or fact."). The differing ages and home states of the plaintiffs have no bearing on the commonality of their claims or the relevant transaction by Appellant.

Joinder is clearly proper here because the plaintiffs' reasonably related claims arise out of the same transaction, occurrence, or series of transactions or occurrences, and because questions of law and fact are shared among each plaintiff's causes of action against Appellant. See Section 507.040.1; Rule 52.05(a); State ex rel. Allen v. Barker, 581 S.W.2d 818, 826 (Mo.banc 1979); Dally, 248 S.W.3d at 617; Saeger, 350 S.W.2d at 821; Kelley, 210 S.W.2d at 729. Appellant's arguments that the claims bear some differences do nothing to disprove the commonalities, and it is the commonalities that permit joinder.

Appellant filed petitions for extraordinary writs in this Court and in the Missouri Supreme Court asserting venue was improper in this case. Appellant's successive petitions for extraordinary writs were denied. Both this Court and the Supreme Court heard Appellant's arguments supporting its position that venue was improper in this case after the issue was fully briefed by both sides in the writ proceedings in both courts. This Court and the Supreme Court individually denied Appellant's petitions, rejecting its improper venue argument. Herein again on direct appeal, we still find no merit in Appellant's contention venue was improper in this case. We find the plaintiffs and their claims were properly joined and thus venue in the City of St. Louis was proper for Respondent.

#### Severance

The decision of whether to allow severance of claims is within the sound discretion of the trial court, and we will not disturb the ruling of the court absent an abuse of discretion. Guess v. Escobar, 26 S.W.3d 235, 239 (Mo.App. W.D. 2000). A discretionary ruling is presumed correct, and an abuse of discretion only occurs where we find the ruling is clearly against the logic of the circumstances and so arbitrary and unreasonable that it shocks the sense of justice. State ex rel. Sago v. O'Brien, 827 S.W.2d 754, 755 (Mo.App. E.D. 1992). In considering whether the trial

court abused its discretion by refusing to sever, we must keep in mind that the policy of the law is to try all issues arising out of the same occurrence or series of occurrences together.

Bhagyandoss v. Beiersdorf, Inc., 723 S.W.2d 392, 395 (Mo.banc 1987).

Rule 66.02 governs severance of claims:

The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, cross-claim, counterclaim, or third-party claim, or of any separate issue or of any number of claims, cross-claims, counterclaims, third-party claims, or issues.

Neither convenience, the avoidance of prejudice, or judicial economy would be served by severance of the plaintiffs' claims against Appellant. This case involves a single defendant's manufacture, design, sale and marketing of a single pharmaceutical drug. Appellant does not cite any Missouri law or controlling precedent in support of its argument the plaintiffs' claims should be severed because trying multiple plaintiffs' claims creates a risk of confusion and the improper consideration of collective evidence by the jury. Any alleged risk in that regard can be prevented by properly instructing the jury. Appellant has failed to show joinder of the plaintiffs' cases contravenes judicial economy or causes it an undue burden as the sole defendant.

We find that the trial court's denial of Appellant's motion to sever is not against the logic of the circumstances, and, therefore, the trial court did not abuse its discretion in denying the motion for severance. Based on the foregoing, Points I and II are denied.

#### Failure to Warn

In its third point, Appellant maintains the trial court erred in denying its motions for DV and JNOV on Respondent's failure to warn claim because the Depakote label was adequate as a matter of Minnesota law in that the label (a) attracted the attention of those to whom it was

directed, (b) explained the mechanism and mode of injury, and (c) explained how to safely use the product to avoid injury.

To determine whether a DV or JNOV should have been granted, this Court applies essentially the same standard. Keveney v. Mo. Military Acad., 304 S.W.3d 98, 104 (Mo.banc 2010). To determine whether the evidence was sufficient to support the jury's verdict, an appellate court views the evidence in the light most favorable to the verdict and gives the plaintiff the benefit of all reasonable inferences. Id., Moore v. Ford Motor Co., 332 S.W.3d 749, 756 (Mo.banc 2011). Conflicting evidence and inferences are disregarded. Keveney, 304 S.W.3d at 104. The jury's verdict will be reversed only if there is a complete absence of probative facts to support the jury's conclusion. Id.

#### Minnesota Law

The parties do not dispute Minnesota law applies here and Minnesota, like Missouri, follows the "learned intermediary doctrine" in prescription drug cases. A physician acts as a "learned intermediary" between the drug manufacturer and the patient and any warning given to the physician is deemed a warning to the patient. Kirsch v. Picker Intern., Inc., 753 F.2d 670, 671 (8th Cir. 1985). In cases involving manufacturers of prescription drugs, the manufacturer has "a duty to properly warn the doctor of the dangers involved and it is incumbent upon the manufacturer to bring the warning home to the doctor." Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo.App. E.D. 1999), quoting Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 146 (Mo.1967). Under the learned intermediary doctrine, the manufacturer has no duty to warn the lay public or patients regarding prescription drugs, but only prescribing physicians. Mulder v. Parke Davis & Co., 181 N.W.2d 882, 885 n.1 (Minn. 1970).

Under Minnesota law, “broadly speaking, a failure to warn claim has three elements: ‘(1) whether there exists a duty to warn about the risk in question; (2) whether the warning given was inadequate; and (3) whether the lack of a warning was a cause of plaintiff’s injuries.’” Huggins v. Stryker Corp., 932 F. Supp. 2d 972, 986 (D. Minn. 2013), quoting Seefeld v. Crown, Cork & Seal Co., 779 F.Supp. 461, 464 (D. Minn. 1991) (citing Balder v. Haley, 399 N.W.2d 77, 81 (Minn. 1987)). Appellant does not dispute it had a duty to warn Dr. Jacoby or that its drug Depakote caused the injuries suffered by Respondent. Rather, Appellant maintains its warning was sufficient. Thus, the only element at issue here is whether the warning given was adequate.

In general, a warning is adequate as a matter of Minnesota law when it: “(1) attract[s] the attention of those [to whom it is directed]; (2) explain[s] the mechanism and mode of injury; and (3) provide[s] instructions on ways to safely use the product to avoid injury.” Gray v. Badger Mining Corp., 676 N.W.2d 268, 274 (Minn. 2004). Appellant maintains its warning about Depakote was adequate as a matter of Minnesota law because it was a black box warning, which Appellant maintains is considered the strongest and most significant way to stress a warning about a drug to a learned intermediary; its warning stated Depakote can cause neural tube defects, such as spina bifida, when used by pregnant women; and its warning indicated the only way to avoid the possibility of spina bifida from Depakote is to either avoid the use of Depakote during pregnancy or avoid getting pregnant while on Depakote.

Appellant maintains it satisfied all three requirements for an adequate warning in this case, and thus the court should have directed a verdict in its favor or issued a JNOV. We disagree.

Appellant's Warning Was Inadequate in Light of its Knowledge

Appellant knew Depakote had an increased overall risk of birth defects versus its competitors and was significantly more dangerous for use in women of childbearing age. Yet, Appellant did not include this information in its warning. Rather, its warning in 1980 remained the same in 2002 despite outdated information, to-wit:

THERE ARE MULTIPLE REPORTS IN THE CLINICAL LITERATURE WHICH INDICATE THAT THE USE OF ANTI-EPILEPTIC DRUGS DURING PREGNANCY RESULTS IN AN INCREASED INCIDENCE OF BIRTH DEFECTS IN THE OFFSPRING. ALTHOUGH DATA ARE MORE EXTENSIVE WITH RESPECT TO TRIMETHADIONE, PARAMETHADIONE, PHENYTOIN, AND PHENOBARBITOL, REPORTS INDICATE A POSSIBLE SIMILAR ASSOCIATION.

Appellant knew of multiple studies concluding that (1) Depakote posed a higher risk of overall birth defects than its competitor AEDs, (2) the overall risk of birth defects was 10 percent or even greater, (3) the risk of spina bifida was significantly higher than the 1-2 percent stated in the label, and (4) the risk of spina bifida amounts to a twentyfold increased risk compared to the background rate in the general population. This information was conveyed at trial to the jury via expert witnesses on the subject and evidence demonstrating it was common knowledge in Appellant's industry – knowledge that was growing every year – that Depakote was by far the most dangerous AED on the market for causing birth defects.

Appellant's Warning Was False and Misleading

Contrary to what it knew to be true, Appellant's label falsely stated sufficient data to determine the incidence of birth defects *was not available*:

OTHER CONGENITAL ANOMALIES (EG, CRANIOFACIAL DEFECTS, CARDIOVASCULAR MALFORMATIONS AND ANOMALIES INVOLVING VARIOUS BODY SYSTEMS), COMPATIBLE AND INCOMPATIBLE WITH LIFE, HAVE BEEN REPORTED. SUFFICIENT DATA TO DETERMINE THE INCIDENCE OF THESE CONGENITAL ANOMALIES IS NOT AVAILABLE.

Appellant was specifically advised that Depakote should not be prescribed to women of childbearing years *unless all other alternatives had been tried and failed* and Appellant was aware of scientific literature concluding the same. This information was not included in the warning to doctors.

Appellant persists in its position it was enough that it just warned of the bottom line risk known since the early 1980s that Depakote could cause birth defects such as spina bifida. Appellant argues it did not have an *added* duty to warn that Depakote's overall risk for all birth defects was higher than that of all other AEDs on the market and therefore Depakote should be used in women of childbearing potential only if all other AEDs failed to control the woman's seizures.

The fatal flaw in Appellant's argument is this is not an *added* duty. Rather, as research revealed and it came to light Depakote was the most dangerous drug for causing birth defects in comparison to other AEDS on the market, the jury found it reasonable that Appellant warn doctors of this fact about its own product, so doctors could make a truly informed decision about what AED to prescribe to their female patients of childbearing potential and only to prescribe Depakote if all others failed. However, Appellant's "2003 Psychiatry Sales & Marketing Tactical Execution Plan" actually stated its objective was "to maintain Depakote's position as a *first-line* agent for women with epilepsy, bipolar, and migraine." (Emphasis added.)

Issues such as the adequacy of the warning, breach of duty and causation are for the jury's resolution. Balder, 399 N.W.2d at 81. The adequacy of the warning must be resolved by the factfinder. Kociemba v. G.D. Searle & Co., 680 F.Supp. 1293, 1301 (D. Minn. 1988).

The Effect of Profits on Warning

Despite conducting no independent research or studies to evaluate Depakote's safety in pregnancy, Appellant spent \$50-100 million per year marketing the drug. This information came from the testimony of Lawrence F. Carbone (Carbone), Appellant's sales director of neuroscience. From 1996, when the use of Depakote was sanctioned for use in migraines and bipolar disease, to 2002, Depakote was by far Abbott's most profitable drug. However, it was also known within Abbott, according to Carbone, as a "dirty drug." The following exchange was held regarding that moniker:

Q. And one reason for that - for calling it a dirty drug would be that there - safety issues have emerged over time with the product, correct?

A. Correct.

Q. And you're aware that one of the safety issues that actually was somewhat of a challenge in marketing was the issue of teratogenicity,<sup>8</sup> correct?

A. Yes.

Q. Now, Mr. Carbone, I assume you were in sales, and at one point you were the director of sales, right?

A. Correct.

Q. Would you agree as a director of sales that the sales team's job was to convince physicians to use Depakote?

A. Depakote, yes, for its indications.

Carbone conceded he wrote an internal memo at Abbott indicating the need to push sales of Depakote to doctors, and admitted the salespeople received bonuses for defeating the competition by convincing doctors to prescribe Depakote. These admissions were followed up by this questioning:

Q. Mr. Carbone, I'm showing you Exhibit 898, and this is an e-mail from Mr. Lavery to Blasine Penkowski and to you, correct?

A. Correct.

Q. What Mr. Lavery writes is: Currently, we are defending a 20-year-old product with significant product liabilities. You see that?

A. Correct.

Q. Was that a true statement?

A. Yes.

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<sup>8</sup> Teratogenicity means "causes birth defects."

Q. And he says: However, recognizing the barriers to securing resources for a product that may be considered a cash cow, the fact of the matter remains we must meet sales objectives for a product that delivers significant profit to the corporation....

Q. Are you looking at Exhibit 901, this page that says: What do we carry forward to 2000?

A. Correct.

Q. And you see the part I'm highlighting here in this Abbott planning document? It says: We must squeeze every dollar and every TRx out of the market in 2000. Right?

A. Yes.

Q. And TRx means prescription, right?

A. Total prescriptions, correct.

Q. So the discussion within Abbott at that point was the directive, we must squeeze every dollar and every prescription we can out of the market, right?

A. Yes.

Thus, despite the knowledge of the harm caused by this known "dirty drug," in the early 2000s Abbott sought to "squeeze every dollar and every prescription" out of the market.

The interview ensues:

Q. And under Recommended Strategy, point one is "aggressively defend brand from competitors." Right?

A. Correct.

Q. And second strategy is to "expand use." And that would be expand use of Depakote, correct?

A. Correct.

Q. And part of the recommended strategy here was to expand Depakote use in women, correct?

A. Correct.

Q. As it states there, knowing teratogenicity and PCOS<sup>9</sup> are the issues. The strategy was then, you know, to expand the use of Depakote in women, correct?

A. Yes.

Q. Okay. The next one is -- I believe this is an e-mail that you wrote. It's Exhibit 913. All right. So Exhibit 913 is an e-mail from you, May 31, 2002, correct?

A. Correct.

Q. And it's to Kevin McRaith and then also your supervisor, Blasine Penkowski, right?

A. Correct.

Q. And what this is, is this is a report by you of comments or questions you grasped during a meeting which involved Jeff Leiden, correct?

A. Correct.

Q. Who is Jeff Leiden?

A. Jeff Leiden was our chief medical officer for the company, Abbott, at the time. So this APU means April update questions. So it was a meeting convened where Blasine and Kevin actually presented and I was the note taker, if you will.

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<sup>9</sup> Polycystic ovary syndrome.

Q. And Mr. Leiden then was one of the most senior executives at the company?

A. Correct.

Q. So let's just leave it at would you agree that Mr. Leiden was one of the senior executives of Abbott?

A. Yes.

Q. And what was that a reference to?

A. I believe it made reference to the clinical data because this is in 2002, and the original data was 1995 or earlier, that we needed more data in that indication.

Q. Point 3 says: When share trend was presented, Jeff said: The share is a decrement. We need to change that or we will die, exclamation point. Correct?

A. Correct. And that could have been collectively because this is the neurology and psychiatry markets. So it could include both psychiatry as well as neurology share, market share, yes.

Q. So at this time, Mr. Leiden, who was an executive, was presented with a market share trend, and it's pretty obvious he was very unhappy with it, correct?

A. Correct.

Q. And he said, we need to change that trend or we will die, correct?

A. Correct.

Q. He was obviously putting people under him on notice that he expected to see sales improve?

A. He wanted market share to increase versus the competitors, correct.

Q. And then under number 6, there's a discussion about strategy. And when it says "he," that's Mr. Leiden again, correct?

A. Correct.

Q. And it says: He is looking for efficacy superiority over the competition because Depakote is a dirty drug so we have to differentiate ourselves. Correct?

A. Yes.

Q. Okay. And that was something again you mentioned. Throughout the company people had occasionally referenced Depakote as a dirty drug?

A. Yeah. That comment, "dirty drug," really came more from outside, and it was referenced inside because that's how people thought of it at times.

Q. And "reference" being a reference to safety issues, correct?

A. Correct.

Q. And one of the safety issues being the birth defect issue, correct?

A. Correct.

At this point, Appellant's "2003 Psychiatry Sales & Marketing Tactical Execution Plan"

was marked Exhibit 914 and introduced.

Q. And the thing I want to ask you about, it talks about the strategic rationale. And if you look at the final sentence there, it says: "Objective is to maintain Depakote's position as a first-line agent for women with epilepsy, bipolar, and migraine via provision of scientific rationale and support to physicians in the treatment of women with these disorders." Correct?

A. Yes.

Q. So would you agree that Abbott desired to maintain Depakote's position as a first-line agent for women with epilepsy or bipolar disorder?

MR. GRAY: And migraine.

Q. That's what the - and migraine?

A. Yes.

Q. And first-line agent means a first choice or the first line - first drug to be used in a disease state, correct?

A. Correct.

In summary, the evidence showed in 2002, Appellant's goals were to expand Depakote use in women and grow market share. Information relating to the risk of birth defects was regarded as an obstacle to sales and damaging to Depakote. Appellant failed to provide accurate information to physicians and correct what was by 2002 misleading information in its warning.

Internal documents and depositions show Appellant's strategy was to expand the use of Depakote in women and maintain Depakote's position as a first line agent for women with epilepsy, bipolar disorder and migraine even though Depakote was known internally as a dirty drug due to safety issues.

Despite conceding they conducted no independent research or studies to evaluate Depakote's safety in pregnancy, Minnesota law dictates Appellant cannot claim ignorance of Depakote's dangers known in the field of pharmaceuticals and teratogenicity. Under Minnesota law, a manufacturer is held to the skill of an expert in its particular field of endeavor, and is obligated to keep informed of scientific knowledge and discoveries concerning that field.

Huggins v. Stryker Corp., 932 F. Supp.2d 972, 987 (D. Minn. 2013). A manufacturer's duty to test its products to discover dangers associated with use of the products is a subpart of the duty to provide adequate warnings of dangers associated with its use. Id.; Kociemba v. G.D. Searle & Co., 707 F.Supp. 1517, 1527–28 (D. Minn. 2013). Thus, if a manufacturer fails to provide a warning of a particular risk and reasonable testing would have made the manufacturer aware of that risk, the manufacturer may be liable for failure to warn. Kociemba, 707 F.Supp. at 1527.

The same is true of a manufacturer's duty to keep informed of scientific knowledge in its field. If a manufacturer fails to provide a warning of a particular risk and a reasonable review of the scientific literature would have made the manufacturer aware of that risk, liability may follow. Huggins, 932 F. Supp.2d 987-88; see also Karjala v. Johns-Manville Prods. Corp., 523 F.2d 155, 159 (8th Cir.1975) (holding that a manufacturer may be held liable for failing to warn if, while held to the knowledge and skill of an expert, it did not disclose to the public those dangers inherent in its product that the application of reasonable foresight would reveal).

Under Minnesota law, a manufacturer's responsibility of keeping informed of current scientific knowledge is relevant to whether a manufacturer knew or should have known of the risks in its product. Harmon Contract Glazing, Inc. v. Libby-Owens-Ford Co., 493 N.W.2d 146, 151 (Minn. Ct. App. 1992). "A manufacturer has a duty to warn of dangers where it knew or should have known of the risk or hazard involved." Id.

The law dictates Appellant had a duty to be apprised of the developments in the growing knowledge in the scientific community of Depakote's serious dangers, and to adequately warn about them. The evidence before the jury indicates Appellant *did in fact know* about the developments, and deliberately chose to omit them, claim ignorance of them, and outright lie about them, thereby depriving Dr. Jacoby of the ability to make an informed decision to not prescribe Respondent's mother Depakote and choose a less dangerous alternative.

#### Dr. Jacoby's Testimony

Dr. Jacoby testified Appellant's warning label told him Depakote had a similar birth defect risk to other AEDs. He testified the Depakote label did not warn of the drug's total risk of birth defects. Rather, the label stated such information was unavailable. Dr. Jacoby testified the warning did not convey Depakote was more dangerous than other AEDs and should not be used

in women of childbearing years unless all other treatments had been tried and failed. Dr. Jacoby testified:

With every medication you have to weigh the benefits, does it work, with the risks. If the benefits are good, that is great, and the risks are low, then you're going to end up with a good combination. If the benefits are good but the risks are way too high, then you're still going to end up with problems, so you wouldn't necessarily use that one.

Dr. Jacoby emphatically stated he would not have prescribed Depakote to Respondent's mother if he had accurate information about Depakote.

The jury had significant evidence and information before it to make a determination, pursuant to Minnesota law, that Appellant's black box warning on its drug Depakote was inadequate due to its insufficiencies in light of the current scientific data and statistics regarding Depakote's serious dangers. The evidence and testimony set forth at trial exposed to the jury Appellant's knowledge of the current data about Depakote, and the numbers in the form of profits Appellant reaped by willfully omitting the extent of the drug's dangers from its warning to doctors to protect its profits. Dr. Jacoby's testimony indicated if he had the full true warning about Depakote's dangers, there would have been one less prescription written, to Respondent's mother. Carbone testified safety issues were an obstacle to marketing Depakote, since the drug was a "cash cow" with "significant product liabilities," according to Mr. Lavery. However, their testimony and in-house memoranda indicated Appellant's goal was to squeeze every dollar and every prescription out of the market for Depakote while it could. The jury could clearly deduce from this evidence that explicit, accurate, and up-to-date warnings were sacrificed in the name of profits at Appellant's company, and further, Appellant intentionally deceived and distorted the truth about Depakote to doctors depriving them of the ability to have all the necessary information to make a considered medical decision as to whether to prescribe the drug.

For the foregoing reasons, a DV or JNOV supplanting or overriding the jury's verdict on Appellant's failure to adequately warn of Depakote's dangers would have been inappropriate. A DV or JNOV is only granted when there is a complete absence of probative facts to support the jury's conclusion. Keveney, 304 S.W.3d at 104. And, in determining whether the evidence supports the jury's verdict, we view the evidence in the light most favorable to the verdict and give the plaintiff the benefit of all reasonable inferences, disregarding inferences and evidence to the contrary. Id., Moore, 332 S.W.3d at 756. Accordingly, Point III is denied.

#### Punitive Damages

In its fourth point, Appellant contends the trial court erred in denying its motions for DV and JNOV on Respondent's demand for punitive damages because Respondent did not present clear and convincing evidence Appellant deliberately disregarded the rights and safety of others in that Appellant warned prescribing physicians of Depakote's risk of spina bifida via a black box warning.

Consideration of the factors set forth in Minnesota's punitive damages statute leads us to believe the jury's award of punitive damages was warranted. Section 549.20.3<sup>10</sup> provides:

Factors. Any award of punitive damages shall be measured by those factors which justly bear upon the purpose of punitive damages, including the seriousness of hazard to the public arising from the defendant's misconduct, the profitability of the misconduct to the defendant, the duration of the misconduct and any concealment of it, the degree of the defendant's awareness of the hazard and of its excessiveness, the attitude and conduct of the defendant upon discovery of the misconduct, the number and level of employees involved in causing or concealing the misconduct, the financial condition of the defendant, and the total effect of other punishment likely to be imposed upon the defendant as a result of the misconduct, including compensatory and punitive damage awards to the plaintiff and other similarly situated persons, and the severity of any criminal penalty to which the defendant may be subject.

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<sup>10</sup> Minn. Stat. Ann. § 549.20 (West 2016).

These nine factors are not exclusive or exhaustive. Out of the nine factors elucidated in Section 549.20.3, the parties submitted the first six to the jury for their consideration: seriousness of hazard; profitability; duration; awareness; attitude; and participation.

The seriousness of Appellant's failure to adequately warn was that it resulted in severe life-altering birth defects, such as Respondent's spina bifida, microcephaly, ocular coloboma, brain malformations, cognitive impairment, paralysis, and neurogenic bowel and bladder.

The jury heard evidence Appellant's focus on profit motivated it to conceal the serious hazards presented by Depakote to women of childbearing potential. Appellant spent \$50-100 million per year marketing Depakote, yet spent no money on conducting independent safety research.

The jury was apprised of Appellant's awareness of studies contradicting its warning label for years but its internal communications demonstrated to the jury it primarily viewed this information as an obstacle to sales. Appellant made no effort to correct this misinformation to prescribing doctors, including Dr. Jacoby. Testimony revealed to the jury the knowledge of Depakote's dangers reached the highest levels of Appellant's company. Despite this knowledge, senior executives wanted market share to increase versus its competitors and thus endorsed and compelled the sales and marketing strategy of promoting Depakote's first-line use in women even though it was known to be a dirty drug whose use should be the last resort among AEDs in childbearing women

The facts presented at trial provide clear and convincing evidence upon which the jury could conclude Appellant deliberately disregarded the safety of Respondent and thus was entitled to have punitive damages assessed against it.

The trial court “specifically reviewed the jury’s \$23 million punitive damages award against [Appellant]” in light of the factors set forth by the Minnesota punitive damages statute. The court held “[b]ased on the facts and evidence presented at trial, the Court finds that the jury’s award of punitive damages was supported by the evidence adduced at trial, in accordance with the statutory factors, and not excessive.” We agree. Point IV is denied.

#### Point V – Evidence

In its fifth point, Appellant argues the trial court committed cumulatively prejudicial evidentiary errors in that it (a) admitted an expert opinion on warning which had not been disclosed prior to trial, (b) admitted evidence of marketing and promotional materials the prescribing physician never saw or was influenced by, and (c) admitted evidence of Appellant’s financial condition during the compensatory damages phase of the trial. Appellant maintains that, at a minimum, it deserves a new trial.

A new trial can be ordered due to cumulative error, even without deciding whether any single point would constitute grounds for reversal. Delacroix v. Doncasters, Inc., 407 S.W.3d 13, 39 (Mo.App. E.D. 2013). However, any number of non-errors cannot add up to an error. Id.

Appellant claims the trial court should not have permitted Dr. Godfrey P. Oakley, Jr., Respondent’s expert “birth defects prevention doctor,”<sup>11</sup> to testify at trial to his opinion Appellant should have warned physicians Depakote’s 1-2% absolute risk of spina bifida translated to a 20-times higher relative risk of spina bifida compared to the general population of

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<sup>11</sup> When asked what qualified him to be a “birth defects prevention doctor,” Dr. Oakley responded, “Well, I have a medical degree. I have training in pediatrics. I have training in epidemiology. And I have training in public health and genetics. And I spent my career at CDC [Center for Disease Control] working on finding the causes of birth defects and preventing causes of birth defects when we found them.” Dr. Oakley was the Chief birth defects doctor at the CDC for many years. He has been a doctor for 50 years and specializes in pediatrics, genetics, and preventive medicine.

patients without epilepsy and who do not take an AED because this warning opinion was not disclosed to Appellant prior to trial.

However, Dr. Oakley did not testify about the black box warning. Rather, he testified at length about the information Appellant had regarding the 20.6 times higher risk without objection. Dr. Oakley testified without objection this risk number was not part of the “Dear Doctor” letter<sup>12</sup> Abbott sent to physicians in 1983. He also testified without objection that the 20.6 relative risk is “the most important number” and he had never seen a drug with this great a risk of birth defects. When speaking about a fellow researcher who discovered this in the 1980s, he said: “And when she did, and she looked and put her data together and it was published, it showed that there was a 20 times chance that this drug [valproic acid] would cause -- would cause spina bifida. It was just an enormous increased risk.” Dr. Oakley further testified:

Q. To your knowledge, has anybody in your lifetime discovered - well, first of all, what was her finding as to the increased risk for a birth defect - this particular birth defect, not all birth defects, just this particular one. What was the increased risk she found in 1982 for valproic acid?

A. It was 20.6. Twenty times.

Q. And if we were to put that in a percentage, it would be what percentage?

A. Two thousand sixty.

Q. So not a ten percent increase, not a 200 percent increase, but a 2,060 percent increase as a result of exposure to valproic acid?

A. That is correct.

Q. So, you know, if you -- for an epidemiologist, a teratologist, a birth defects doctor, when you saw that number, how'd you react?

A. Well, we knew we had a new powerful cause of human birth defects. And that led us to have the dream of stopping these birth defects caused by this drug from happening. And we knew theoretically what needed to be done was not to have any pregnant woman exposed to this drug.

This information was repeated many times during his testimony. Whenever Dr. Oakley was asked his opinion about what Appellant should have done with regard to warning of this

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<sup>12</sup>A Dear Doctor letter is a way that drug companies send out an important message about the drug that they sell.

danger, Appellant objected and the court sustained the objection. One time the court overruled the objection, because the question posed was whether in Dr. Oakley's opinion the 20.6 times higher relative risk, known by Appellant at the time, should have been disclosed in Appellant's 1983 Dear Doctor letter, not the label or black box warning. This material was all covered before trial, and accordingly, Appellant's claim of unfair surprise, trial by ambush, and prejudice is without merit.

Appellant also claims evidentiary error in the court's admission of marketing and promotional materials Appellant contends Dr. Jacoby never saw or was influenced by in prescribing Depakote to Respondent's mother. Appellant does not specify or describe these marketing and promotional materials. Further, whether the materials were seen by and influenced Dr. Jacoby to prescribe Depakote to Respondent's mother is not the exclusive relevant use for them. For example, they demonstrate Appellant's knowledge and motive with regard to Depakote's risk and its failure to adequately warn about its dangers.

Appellant's last evidentiary complaint is the trial court's allowance into evidence during the compensatory damages phase of the trial its \$1.1 billion from sales of Depakote in 2002, and sales figures from various other unspecified years. Appellant speculates this information was prejudicial because it could have caused the jury to award damages to Respondent merely based upon Appellant's ability to pay. However, information about Appellant's profits from its sale of Depakote is relevant to its motive in promoting the drug despite and without sufficient regard for the danger to pregnant women and its failure to adequately warn about those dangers in order to protect its profits from the drug.

None of these evidentiary rulings prejudiced Appellant to the extent a new trial is warranted. Point V is denied.

Conclusion

The trial court's judgment is affirmed.

  
Sherri B. Sullivan  
SHERRI B. SULLIVAN, P.J.

Philip M. Hess, C.J., concurs;  
Roy L. Richter, J., concurs in separate opinion.



## In the Missouri Court of Appeals Eastern District

### DIVISION TWO

MIASIA BARRON, et al.,	)	No. ED103508
	)	
Plaintiffs,	)	Appeal from the Circuit Court
	)	of the City of St. Louis
and	)	
	)	
MADDISON SCHMIDT,	)	
	)	
Plaintiff/Respondent,	)	
	)	
v.	)	
	)	
ABBOTT LABORATORIES, INC.,	)	Honorable Steven R. Ohmer
	)	
Defendant/Appellant.	)	Filed: November 8, 2016

### CONCURRING OPINION

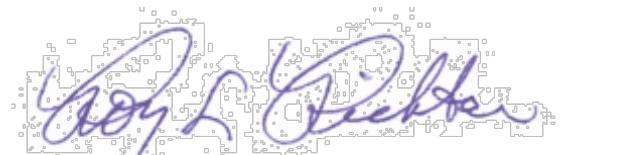
I concur in the result that the plaintiffs and their claims were properly joined and thus venue in the City of St. Louis was proper for Respondent because we must follow Missouri law and precedent. Doe v. Roman Catholic Diocese of St. Louis, 311 S.W.3d 818, 822 (Mo. App. E.D. 2010). “Where the language of the statute is unambiguous, courts must give effect to the language used by the legislature.” State v. Burns, 978 S.W.2d 759, 761 (Mo. banc 1998). Courts may not “read into a statute a legislative intent contrary to the intent made evident by the plain language.” Keeney v. Hereford Concrete Prods., Inc., 911 S.W.2d 622, 624 (Mo. banc 1995).

Section 508.010, in relevant part, states:

1. As used in this section, “principal place of residence” shall mean the county which is the main place where an individual resides in the state of Missouri. There shall be a rebuttable presumption that the county of voter registration at the time of injury is the principal place of residence. There shall be only one principal place of residence.  
...
4. Notwithstanding any other provision of law, in all actions in which there is *any count alleging a tort and in which the plaintiff was first injured in the state of Missouri, venue shall be in the county where the plaintiff was first injured by the wrongful acts or negligent conduct alleged in the action.*  
...
14. A plaintiff is considered first injured *where the trauma or exposure occurred rather than where symptoms are first manifested.*

Section 508.010 (emphasis added).

When combined with Missouri Supreme Court Rule 52.05, the result is that lawsuits are filed in Missouri with a minimal number of Missouri plaintiffs joined with a much larger number of non-resident plaintiffs. To the extent that this practice is seen as a problem, it is within the power of the Legislature to “fix it.”



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ROY L. RICHTER, Judge